

SENSUS[®]

PAIN MANAGEMENT

User Manual

GET RELIEF



GET ACTIVE



GET SLEEP



NEUROMetrix[®]

TABLE OF CONTENTS

| | |
|---|-----------|
| Chapter 1: Pain Relief with SENSUS..... | 3 |
| Introduction | 3 |
| What You Should Have Received..... | 4 |
| Device Components..... | 6 |
| Chapter 2: Getting Started..... | 7 |
| Chapter 3: Device Basics..... | 9 |
| Checking Battery | 9 |
| Charging Battery | 9 |
| Attaching Electrode | 11 |
| Device Placement..... | 12 |
| Chapter 4: Configuration | 13 |
| Chapter 5: Pain Therapy | 14 |
| Preparing for Therapy Session | 14 |
| Starting Therapy Session | 15 |
| Adjusting Intensity During Therapy Session..... | 15 |
| Ending Therapy Session..... | 16 |
| Chapter 6: Overnight Therapy | 17 |
| Chapter 7: Electrodes | 17 |
| Chapter 8: Skin Care..... | 18 |

TABLE OF CONTENTS CONT.

| | |
|--|-----------|
| Chapter 9: Maintenance, Safety, and Service | 21 |
| Maintenance..... | 21 |
| Cleaning | 21 |
| Device Storage..... | 22 |
| Disposal..... | 22 |
| Limited Warranty | 22 |
| APPENDIX A: Indicator Light..... | 24 |
| APPENDIX B: Troubleshooting | 25 |
| APPENDIX C: Frequently Asked Questions | 28 |
| APPENDIX D: Alternate Placement Sites | 33 |
| APPENDIX E: Automatic Restart..... | 34 |
| APPENDIX F: Technical Specifications | 35 |
| APPENDIX G: Prescribing Information | 38 |
| APPENDIX H: Symbols..... | 42 |
| APPENDIX I: Electromagnetic Compatibility Declaration | 43 |

Chapter 1: Overview

Introduction

The SENSUS® Pain Management System is an innovative wearable medical technology that provides relief from chronic pain. It consists of a device and an electrode that attaches to the device. The device is worn on your upper calf, a few inches below the knee, and is controlled by a single button.

SENSUS provides pain relief by comfortably stimulating the nerves that carry normal, non-painful sensations to your brain. Electrical stimulation of these nerves is believed to change the levels of certain natural chemicals in your nervous system that decrease your pain.

Pain relief is initiated by simply pressing a button on the device. Each therapy session is 60 minutes. After your first session, therapy will automatically restart every other hour. Pain relief usually begins within 15 minutes of the start of a therapy session and may last up to an hour following the end of a session. You have complete control and can start or end therapy anytime.

You should review this User Manual carefully. Chapter 2 shows you how to get started. Chapters 3–5 provide detailed instructions on device use. Chapter 6 describes device use during sleep. Chapter 7 offers tips for taking care of the electrodes. Chapter 8 provides information on preventing skin irritation, particularly if you have sensitive or dry skin. Appendix C gives answers to frequently asked questions.

If you have any questions about how to use SENSUS please call NeuroMetrix customer service at (888) 786-7287.

What You Should Have Received

Upon receiving your SENSUS Pain Management System you should inspect its contents to make sure all of the following are included and undamaged (see Figure 1).

- A.** SENSUS Device
- B.** Small and Large Replacement Straps
- C.** USB Cable
- D.** AC Adapter
- E.** User Manual

You may also have received electrode packages (Figure 2). If any of the items appear damaged, contact your supplier.

Figure 1.



Figure 2.



Device Components

The device has the following components:

- 1 Push button
- 2 Indicator light
- 3 Adjustable Velcro® strap
- 4 Two electrode connector snaps
- 5 USB port (not seen in image, port is on side of device)



Chapter 2: Getting Started

The following instructions will help you start using SENSUS. For additional details, please review Chapters 3-8.

These instructions are also available in video format at: www.SENSUSRx.com/Instructional/video.html

Step 1: Check Battery

Briefly press the button.



charged



recharge



Step 2: Attach Electrode

Snap in a new electrode.



Step 3: Place Device

Remove liner and place the device on the upper calf of either leg, 1-2 inches below knee. The exact position is not critical.



Step 4: Configure (First Use Only)

You must configure your device before first use. Press and hold button for 10 seconds until the indicator light is steady green.


Briefly press the button whenever you feel a sensation under the electrode. The sensation will pause with each button press. You will typically press 3-6 times. When the light turns off, you are done configuring your device.




Step 5: Start Therapy

Briefly press the button. The indicator light will blink green and the intensity will automatically increase to your therapeutic level over 2 minutes. You should feel a strong but comfortable sensation.



 **Intensity:** Briefly press the button; each press decreases intensity.

 **Intensity:** Hold button down; intensity will increase while button is down.

 **Therapy:** Press button 4 times to stop therapy.

A therapy session lasts 1 hour. After starting your first session, therapy will automatically restart every other hour.

 **Air-out skin after wearing several hours or overnight; device will pulse on and off for 1 minute as a reminder.**

Helpful Tips

- Entire electrode should contact skin
- Every few hours, make sure device fits securely around your leg
- Run electrode under water if it stops adhering to skin
- Change electrode every 2 weeks

If you need assistance, call 1-888-786-7287.

Chapter 3: Device Basics

Checking Battery

With the device in your hand, briefly press the button to check the battery (Figure 3). The indicator light will flash green if the battery has sufficient charge. If indicator light flashes red or does not flash at all, the battery needs to be recharged (see below for charging instructions).

Figure 3.



 **charged**

 **recharge**

Charging Battery

A fully charged battery typically provides 20-40 hours of use.

To charge the battery:

1. Plug the USB cable into the USB port on the side of the device.
The USB port is protected by a rubber cover. To access the USB port, rotate the cover until the connector is exposed (Figure 4).

Figure 4.



2. Plug the other end of the cable into the AC Adapter (Figure 5). The cable should not be plugged into a computer USB port for charging.

Figure 5.



3. The AC Adapter should then be plugged into a standard electrical outlet (Figure 6). The indicator light on the device will show steady green during charging and will turn off when the battery is fully charged. It will take approximately 3 hours to charge an empty battery. When the battery is fully charged, unplug the cable from the device.

Figure 6.



If the light blinks red while device is connected to the outlet, charging has failed.

If the battery is too low to start a therapy session, you can charge the device for approximately 20 minutes to provide enough charge for one therapy session. To confirm, disconnect the USB cable from the device and briefly press the button. If the indicator light flashes green, battery has enough charge. If the indicator light flashes red, reconnect the USB cable and continue charging.



Do not use your device with the USB cable connected.

Device Placement

Place the device on your upper calf about 1-2 inches below the knee (Figure 10). You may place on either leg. Be sure the electrode is only covering healthy skin that is not irritated and does not have cuts or other wounds. Position the device so that it is comfortable, the button is accessible, and you experience a comfortable sensation during therapy. You may position the device with the button on the inside, outside, or back of the leg. You should avoid placing the center compartment directly over your shinbone.

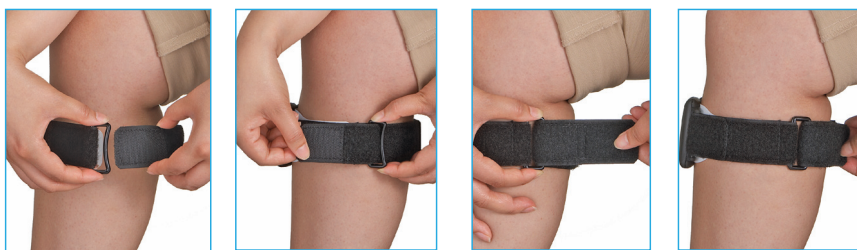
Figure 10.



If the device cannot be placed in the standard location as shown in Figure 10 then refer to Appendix D for alternate site options.

Loop the strap through the buckle and attach it with the Velcro® fastener as shown in Figure 11. The device should fit securely around your leg and be comfortable to wear. However, the strap should not be so tight that the device and electrode substantially indent the skin. The electrode should make smooth contact with the skin. If there is buckling of the electrode, loosen the strap, smooth the electrode and re-secure the strap. It is important that all four electrode pads are in contact with your skin. If the pads are only partially on the skin, then the stimulation may feel uncomfortable.

Figure 11.



Your device comes with small, medium and large straps. It is shipped with the medium strap attached. If you require a different strap, remove the medium strap and attach either the small or large strap.

Chapter 4: Configuration

Before you begin using your device for the first time you will need to configure. You should also reconfigure your device if you are no longer experiencing pain relief. **Otherwise you do not need to reconfigure your device**, including when you switch electrodes and alternate legs.

You should carry out the configuration process in a quiet area without distractions. It is best to configure using a new electrode.

Configuration Procedure

STEP 1 Snap in a new electrode.

STEP 2 Remove liner and place the device on the upper calf of either leg, 1-2 inches below knee. The exact position is not critical.

STEP 3 Press and hold button for 10 seconds until the indicator light is steady green. Briefly press the button whenever you feel a sensation under the electrode. The sensation will pause with each button press. You will typically press 3-6 times. When the light turns off, you are done configuring your device.

If your doctor prescribed two devices, configure one device at a time. If you have difficulty with configuration, call (888) 786-7287.



Device is configured for a single person and should not be shared.

Chapter 5: Pain Therapy

During a therapy session, the device will comfortably stimulate the nerves in your leg to provide pain relief. Each therapy session lasts 60 minutes, and a new session will automatically restart every other hour. See Appendix E to turn automatic restart off.

To maximize pain relief, you should feel a strong but comfortable sensation. The intensity that you will require is estimated based on your device configuration. However, because of differences among people, this estimated intensity may be too low and feel weak, or too high and feel uncomfortable. In either case, you should adjust the intensity as described on page 15. The greatest pain relief will be obtained when you set the intensity to the highest level that is also comfortable. The device will remember changes to the intensity and you should not need to adjust often. Please follow the steps on the following pages for a therapy session.

Preparing for Therapy Session

Before starting a therapy session make sure you have an electrode attached to the device. You should also check the battery to ensure it has an adequate charge. Place the device on your leg as described in Chapter 3.

Starting Therapy Session

To start a therapy session, briefly press the button (Figure 13). The indicator light will blink green for the duration of the therapy session.

The intensity will gradually increase over the first two minutes to the intensity that was determined when you configured your device. This intensity will be stronger than what you experienced during configuration. You may not feel anything for the first 10-15 seconds, however, the blinking green light indicates the device is functioning properly. Therapy will continue for 60 minutes. You may feel a strong sensation at first but it will typically fade to a comfortable level after a couple of minutes. If the sensation is uncomfortable or painful, you should decrease the intensity as described in the next section.



Once your therapy session has begun, you may cover the device with your clothing. You should be careful not to dislodge the device and electrode when covering with clothing. It is best to wear loose fitting clothing so that you can access the device. You may go about your normal activities during a therapy session. Do not shower, bathe or swim with the device on your leg.

Figure 13.



Adjusting Intensity During Therapy Session

Frequent adjustments should not be necessary; however, if the sensation is not strong, if it feels uncomfortable, or your calf muscle is twitching, please follow the instructions below:

-  **Intensity:** Briefly press the button; each press decreases intensity.
-  **Intensity:** Hold button down; intensity increases while button down.

You may adjust the intensity at any time during a therapy session.

i Maximum pain relief will be obtained at the highest intensity that is also comfortable.

Ending Therapy Session

A therapy session stops after 60 minutes. If the device is on your leg, a new therapy session will automatically restart 60 minutes following the end of prior session.

To end a therapy session early press the button 4 times (Figure 14). **You should not remove the device while it is stimulating**, so make sure that the indicator light is not blinking green before removing the device and electrode from your leg.

Figure 14.



After completing a therapy session, you may either leave the device on your leg or remove it. If you remove the device, be careful not to damage the electrode and remember to reapply the liner (see page 18 for instructions on removing electrode).

If you leave the device on your leg for long periods of time, you should check your skin frequently to make sure that it does not get irritated. Chapter 8 provides information on skin care.

If a problem arises during a therapy session, stimulation will stop and the indicator light will blink red for 2 minutes. Refer to Appendix B for troubleshooting assistance.

i Air-out skin after wearing several hours or overnight; device will pulse on and off for 1 minute as a reminder.

Chapter 6: Overnight Therapy

You may use SENSUS at bedtime and throughout the night if pain is preventing you from falling asleep or maintaining high quality sleep.

Before going to sleep, make sure the device is placed securely and comfortably around your leg. Start a therapy session by briefly pressing the button. This first therapy session will stimulate at your regular intensity level. Subsequent therapy sessions will start automatically every other hour throughout the night. If you are asleep during these sessions, the device will automatically lower the intensity. The light will blink green at a slower rate during these sleep sessions.

i Air-out skin after wearing SENSUS overnight.

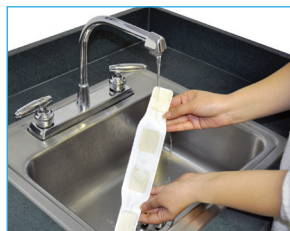
i If you have concerns about the amount or quality of your sleep, please discuss with your doctor.

If you have any questions regarding overnight use of SENSUS call (888) 786-7287.

Chapter 7: Electrodes

The SENSUS Electrodes are designed to operate for 2 weeks (can be extended up to 3 days if a new electrode is not available). You should hydrate your electrode if the gel pads stop adhering to your skin. Run the electrode under a gentle water stream for 10 seconds as shown in Figure 15. Let air dry before using.

Figure 15.



Electrode Removal

You should be careful not to damage the electrode when you remove it from your upper calf area. Slowly peel the electrode from your skin, while making sure that each of the gel pads does not separate from the electrode (see Figure 16). Avoid touching the gel with your fingers as that can damage the gel and decrease the life of the electrode. After removal of the electrode you should cover it with the liner.

Figure 16.



If you have difficulty removing the electrode, refer to Chapter 8.

Electrode Storage

Electrodes should always be stored with the liner covering the gel pads. You may snap the electrode into the device for convenient storage. Electrodes should be stored at room temperature out of direct sunlight.


Electrode Replacement

The electrode should be replaced prior to two weeks if stimulation becomes painful despite hydrating the electrode gel pads and positioning the device so that the entire electrode is making smooth contact with the skin.

Chapter 8: Skin Care

SENSUS works by electrically stimulating your sensory nerves through your skin. Some people have dry or sensitive skin, and it is important to regularly monitor your skin where it contacts the

electrode to ensure that skin irritation does not occur. If your skin becomes irritated, using the device may be uncomfortable. There are some simple things you can do to take care of your skin while using SENSUS.

 **Never use the device on open wounds or rashes or over swollen, red, infected, or inflamed skin.**

Keep Your Skin Moisturized

Dry skin can make the electrodes difficult to remove which can potentially damage the electrode gel.

If you have dry skin or notice that electrode gel comes off the electrodes when removing from the skin, you should consider using a light lotion 30 minutes prior to SENSUS use.

Lotions that are light, non-greasy, fast-absorbing, and intended for daily use will work best. Some examples include:

- Aveeno® Daily Moisturizing Lotion
- Lubriderm® Daily Moisture Lotion
- Gold Bond® Skin Therapy Lotion
- Curel® Daily Moisture Lotion

Make sure the lotion has absorbed fully into the skin before placing the electrode and device.

Prevent Skin Irritation

Air Out Skin

Air-out skin after several hours of use during the day or after overnight use. Switch leg on which device is placed when convenient.

Do Not Over Tighten Band

The strap should not be so tight that the device and electrode indent the skin.

If you have sensitive skin, you may also consider the following:

Start Slow

Limit the time the device is on your skin to 3–4 hours per day in the first week. If you do not experience irritation you may increase use while closely monitoring your skin.

Use Skin Protectant

Apply a skin protectant before placing the device on your leg. Skin protectants are available as wipes, swabs, or sprays. They are safe and may reduce the likelihood of irritation. They also increase adhesion of the electrode to your skin. Protectants that work well include:

- 3M Cavilon™ No Sting Barrier Film
- Smith & Nephew SKIN-PREP®
- Smith & Nephew No-Sting SKIN-PREP®
- Coloplast Prep™ Protective Skin Barrier

These products are available online.

Check for Skin Irritation

Check for signs of irritation, including:

- Skin itches while device is on the skin or after removal
- Skin is red where it contacted electrode
- Raised or reddened hair follicles

If skin irritation develops then you should not place the device over the irritated area until it completely heals. You may apply a topical steroid cream to help accelerate healing and reduce irritation. You may place the device on the other leg or use different locations as shown in Appendix D.

If you experience skin irritation, then you should limit device use to 3 hours per day for a week to make sure that further irritation does not occur.

Chapter 9: Maintenance, Safety, and Service

Maintenance

Contact your supplier if the device requires service.

Cleaning

Use a damp cloth moistened to clean the exterior of the device. Do not use any other cleaning solutions since they may damage the case. Never immerse the device in water or other liquids.

Device Storage

When device is not in use, place it in the carrying case and store it in a dry location away from direct sunlight.

Disposal

Used electrodes should be disposed in normal trash receptacles. Dispose of the device according to national, state, and local regulations as the device contains a Lithium-Ion battery.

Limited Warranty

NeuroMetrix, Inc. manufactures its hardware products in accordance with industry standard practices. NeuroMetrix warrants the SENSUS device to be free from defects in materials and workmanship at the time of shipment. The warranty term is five years beginning on the date of shipment from the manufacturer, as further described in the following text.

This warranty does not cover damage due to external causes, including accident, abuse, misuse, problems with electrical power, usage not in accordance with product instructions, failure to perform required maintenance, and problems caused by use of parts or components not supplied by NeuroMetrix. This warranty does not apply to any product repaired or altered by anyone other than NeuroMetrix or an authorized NeuroMetrix representative.

NeuroMetrix will repair or replace products that are shown to be other than as warranted above and covered under this limited warranty that are returned to NeuroMetrix under a NeuroMetrix issued Return Material Authorization (RMA) Number. To initiate a return contact your supplier.

All parts removed from repaired products will become the property of NeuroMetrix. If NeuroMetrix repairs or replaces a product, the original warranty is not extended.

NEUROMETRIX MAKES NO EXPRESS OR IMPLIED WARRANTIES OR REPRESENTATIONS BEYOND THOSE STATED IN THIS WARRANTY STATEMENT. NEUROMETRIX DISCLAIMS ALL OTHER WARRANTIES AND REPRESENTATIONS, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE.

NEUROMETRIX'S OBLIGATIONS FOR ANY FAILURE OF A PRODUCT TO BE AS WARRANTED ARE LIMITED TO, AT NEUROMETRIX OPTION, REPAIR OR REPLACEMENT OF THE PRODUCTS SET FORTH IN THIS WARRANTY STATEMENT.

UNDER NO CIRCUMSTANCES WILL NEUROMETRIX BE LIABLE FOR ACTUAL OR CLAIMED DEFECTS IN ANY PRODUCT BEYOND THE REMEDIES SET FORTH IN THIS WARRANTY STATEMENT. IN NO EVENT SHALL NEUROMETRIX BE LIABLE FOR SPECIAL, INCIDENTAL OR CONSEQUENTIAL DAMAGES ARISING OUT OF OR IN CONNECTION WITH THIS AGREEMENT REGARDLESS OF THE LEGAL THEORY UPON WHICH SUCH CLAIM IS BASED AND EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY THEREOF.

APPENDIX A: Indicator Light

| Indicator Light Status | Explanation |
|---------------------------|---------------------------|
| Blinking Green* | Stimulating |
| Blinking Red | Error |
| Solid Green | Configuration in progress |
| Single Green Flash | Adequate battery charge |
| Single Red Flash | Battery requires charging |

*Blink rate is once per second except when you are sleeping which will be once every 5 seconds.

APPENDIX B: Troubleshooting

Configuration:

I cannot start the configuration procedure (light is not steady green).

Make sure the device and electrode are properly placed on the leg and the liner has been removed. Press and hold the button down for at least 10 seconds until the light turns steady green.

I am trying to configure, but I do not feel anything.

It may take 20-30 seconds to first feel a sensation.

Therapy:

Therapy can only be initiated after the device and electrode are properly placed on the calf (Chapter 5).

When I start therapy all I see is a single red blink.

Recharge device.

When I start therapy the light blinks green a few times and stops.

Configure device.

Therapy stopped and the light is blinking red.

A blinking red light indicates poor contact between the electrode and the skin. This may occur because the device is not securely placed on the leg or because the electrode is dry. Check that the electrode is snapped in, the electrode is in complete contact with the skin and start therapy again. If the problem recurs, remove the device and inspect the electrode. If the gel is dry then hydrate as described in Chapter 7. Place the device back on the leg and

APPENDIX B: Troubleshooting CONT.

restart the therapy session. If the problem persists, then replace the electrode.

The light is blinking green but I do not feel anything.

Wait until therapy has run for at least 2 minutes. If, after 2 minutes, you still cannot feel anything, the intensity is too low. Press and hold the button to increase the intensity until you have a strong but comfortable sensation. Alternatively, configure the device again.

What should I do if therapy stings or feels uncomfortable?

Turn off the device by pressing button 4 times. Remove the device and inspect the electrode. If the gel is dry, then hydrate the electrode (Chapter 7). If your skin is dry then consider using skin moisturizer (see Chapter 8). Place the device and electrode back on your leg, making sure that there is complete contact between the electrode and the skin. If the discomfort persists then replace the electrode.

What should I do if I get cramps under the device?

You should lower the intensity by briefly pressing the button.

I am not getting pain relief.

Make sure you feel a strong but comfortable sensation. Either increase the intensity by pressing and holding the button or configure the device again.

Electrode Care:

The gel sticks to my skin when I remove the electrode.

If the gel is coming off the electrode then use of a light lotion 30 minutes prior to therapy should help (see Chapter 8).

The gel is dry and losing its stickiness.

You should hydrate the electrodes as described in Chapter 7.

Skin Care:

My skin is irritated (redness or rash) or itches after I remove the device.

Skin irritation may occur. The skin should be aired-out after wearing for 4 hours and after overnight use by removing the device and electrode from the leg. Legs should be alternated. Chapter 8 provides information on skin care.

If you need assistance, call (888) 786-7287.

APPENDIX C: Frequently Asked Questions

What should therapy feel like?

You should feel a vibrating or light pressure sensation. You may reduce the intensity if it feels uncomfortable.

How often can I use SENSUS?

You may start a therapy session whenever you need pain relief. However, it is best to wait one hour between sessions.

When do I need to configure my device?

You must configure the device before first use. You may repeat configuration if pain relief has diminished.

Do I need to configure the device before each therapy session?

No. Once your device is configured you do not need to configure it again unless pain relief has diminished.

Do I need to reconfigure when I switch legs?

No.

If I have foot pain, should I position the device closer to my foot?

No, you should position the device on your upper calf 1-2 inches below the knee as described in Chapter 3.

Can I place the device on my arms or lower back?

No.

If I was prescribed two devices, do I need to match devices and legs?

No, unless the stimulation feels dramatically different between legs.

Will pain relief start immediately after I press the button?

Pain relief usually starts within 15 minutes.

Will pain relief continue beyond the end of the therapy session?

Pain relief may last up to an hour after the session ends.

How often do I need to change the electrode?

Every 2 weeks (can be extended up to 3 days if a new electrode is not available).

Can I use my device while showering or bathing?

No.

Are there side effects?

No. You may experience some mild skin irritation under the electrodes with prolonged use.

Can I use it with pain medications?

Your doctor may decide to prescribe both SENSUS and pain medications.

APPENDIX C: Frequently Asked Questions CONT.

Can multiple people share the device?

No. The device is configured for one person and should not be shared.

Will I get pain relief in just the leg that has SENSUS?

You may experience relief in both legs with placement on one leg.

Will SENSUS just provide pain relief in the legs?

You may experience relief in other body locations.

Can I use SENSUS while sleeping?

Yes.

I have chronic pain, will SENSUS help me sleep better?

It may reduce your pain as you fall asleep and while you are sleeping.

What does SENSUS do while I am sleeping?

It starts 60 minute therapy sessions every other hour throughout the night to control your pain.

Will therapy wake me up?

The device detects that you are sleeping and decreases the intensity to minimize sleep disruption.

Do I need to set up SENSUS differently for sleep use?

No.

What if I only want a single 60 minute therapy session?

Turn automatic therapy restart off (Appendix E).

What should I do before going to sleep?

Make sure the device is securely and comfortably placed around your leg. Start the first therapy session by briefly pressing the button.

Will wearing SENSUS overnight irritate my skin?

You should air-out your skin every morning. You should also alternate legs.

Can I use SENSUS every night?

Yes, however you should alternate legs to decrease the risk of skin irritation.

Will SENSUS reduce or eliminate my need for sleep medications?

Only your doctor can decide whether changes to your medications are appropriate.

APPENDIX C: Frequently Asked Questions CONT.

Does SENSUS treat obstructive sleep apnea?

No.

Can I use SENSUS at the same time as a continuous positive airway pressure (CPAP) machine?

Yes.

Will SENSUS help my insomnia?

There are many causes for insomnia, including chronic pain. Please discuss with your doctor.

What should I do if I have concerns about my sleep?

Poor sleep can impact your health, safety, and quality of life. Please discuss with your doctor.

APPENDIX D: Alternate Placement Sites

If your SENSUS device cannot be placed at its usual location just below the knee, such as due to a wound or skin irritation, then it may be positioned at one of the following alternate sites:

- At mid-calf as shown in Figure 17.
- Above the knee on the lower thigh as shown in Figure 18.

You should configure the device at the new site before initiating therapy.

Figure 17.



Figure 18.



APPENDIX E: Automatic Restart

You may toggle the automatic therapy restart from on to off or vice versa. With the device in your hand, without an electrode attached, press the button for at least 10 seconds, and you will then see either a green or red light. A green light means the automatic restart is on; a red light means the automatic restart is off.

APPENDIX F:

Technical Specifications

Output

| | |
|--|---|
| Waveform | Biphasic with alternating leading phase, symmetrical, rectangular |
| Regulated Current or Voltage | Current |
| Net Charge per Pulse | $0 \pm 1 \mu\text{C}$ into 500Ω load |
| Maximum Output Voltage ($\pm 10\%$) | 100 V |
| Maximum Output Current ($< 1\text{K}\Omega$ load) ($\pm 10\%$) | 100 mA |
| Pulse Duration ($\pm 4\%$) | 200 - 400 μsec |
| Pulse Frequency ($\pm 4\%$) | 60-100 Hz, randomly varying |
| Pulse Pattern | Continuous |
| Maximum Phase Charge | 20 μC |
| Maximum Current Density | 0.71 mA/cm^2 into 500Ω load |
| Maximum Average Current | 4 mA into 500Ω load |
| Maximum Average Power Density | 7 mW/cm^2 into 500Ω load |

Output Trips

| | |
|----------------------------|---------------------------------|
| No Load | Device not connected to patient |
| Insufficient Charge | Delivered charge below target |
| Over Load | Delivered charge above target |
| Short Circuit | Low impedance |
| Electrode Peeling | Electrode dislodging from skin |

APPENDIX F:

Technical Specifications CONT.

Therapy Session

| | |
|---|---|
| Timer | 60 minutes |
| Start Therapy | Briefly press button |
| Halt Therapy | Press button 4 times within 10 seconds |
| Manual Intensity Increase/Decrease | Increase +1.25% per second, decrease -5% |
| Habituation Compensation | Adaptive stepwise increase in intensity of during session |

Electrode

| | |
|-----------------------------|--|
| Type | Self-adhering, single-patient use, multiple applications |
| Materials | Mylar substrate, silver electrode pads |
| Number of Electrodes | 2, outer electrode area 28 cm ² , inner electrode area 33 cm ² |
| Connector | Medical snap (male) |
| Dimensions | 0.2 cm x 5.3 cm x 28.3 cm (exterior) |

Power

| | |
|------------------------|---------------------------------------|
| Source | Permanent rechargeable battery |
| Battery Type | Rechargeable 3.7V Lithium-Ion battery |
| Charging Source | AC line adapter |

Power continued

| | |
|---|------------------------------------|
| Line Current Isolation | Patient disconnected when charging |
| Patient Leakage Current, DC | < 10 μ A |
| Patient Leakage Current, Enclosure | < 100 μ A |

Physical

| | |
|--------------------------------|------------------------|
| Dimensions | 176 mm x 63 mm x 15 mm |
| Weight (without straps) | 82 g |

Environmental

| | |
|--|-------------------|
| Operating Temperature Range | 10° C to 40° C |
| Atmospheric Pressure Range | 50 kPa to 106 kPa |
| Relative Humidity Range | 30% to 75% |
| Transport and Storage Temperature Range | -40° C to 50° C |
| Atmospheric Pressure Range | 50 kPa to 106 kPa |
| Relative Humidity Range | 10% to 90% |

Guidance Documents & Standards

| | |
|-----|---|
| FDA | Draft Guidance for Industry and Staff: Class II Special Control Guidance Document: Transcutaneous Electrical Nerve Stimulator for Pain Relief (April 5, 2010) |
| IEC | IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 62304 |

APPENDIX G: Prescribing Information

UNITED STATES FEDERAL LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN OR LICENSED MEDICAL PROFESSIONAL.

Indications

The NeuroMetrix SENSUS is intended for use as a transcutaneous electrical nerve stimulation device for the symptomatic relief and management of chronic intractable pain. The device may be used during sleep.

Contraindications

- Do not use this device on patients who have a cardiac pacemaker, implanted defibrillator, or other implanted metallic or electronic device, because this may cause electric shock, burns, electrical interference, or death.
- The device should not be used on patients whose pain syndromes are undiagnosed.

Precautions

- Transcutaneous electrical nerve stimulation is not effective for pain of central origin, including headache.
- Transcutaneous electrical nerve stimulation is not a substitute for pain medications and other pain management therapies.
- Transcutaneous electrical nerve stimulation devices have no curative value.
- Transcutaneous electrical nerve stimulation is a symptomatic treatment and, as such, suppresses the sensation of pain that would otherwise serve as a protective mechanism.

- Effectiveness is highly dependent upon patient selection by a licensed medical professional qualified in the management of pain patients.
- The long-term effects of electrical stimulation are unknown.
- Since the effects of stimulation of the brain are unknown, stimulation should not be applied across the head, and electrodes should not be placed on opposite sides of the head.
- The safety of electrical stimulation during pregnancy has not been established.
- Some patients may experience skin irritation or hypersensitivity due to the electrical stimulation or electrical conductive medium (gel).
- Patients with suspected or diagnosed heart disease should follow precautions recommended by their physicians.
- Patients with suspected or diagnosed epilepsy should follow precautions recommended by their physicians.
- Use caution when the patient has a tendency to bleed internally, such as following an injury or fracture.
- Use caution following recent surgical procedures when stimulation may disrupt the patient's healing process.
- Use caution if stimulation is applied over the menstruating or pregnant uterus.
- Use caution if stimulation is applied over areas of skin that lack normal sensation.
- Keep this device out of the reach of children.
- Use this device only with the leads, electrodes, and accessories recommended by the manufacturer.

APPENDIX G:

Prescribing Information CONT.

- Use this device only under the continued supervision of a licensed medical professional.
- Accessory equipment connected to the USB port must be certified to the respective IEC standards (e.g. IEC 60950 for data processing equipment and IEC 60601-1 for medical equipment). Most computers manufactured by major suppliers meet the IEC 60950 standard. If in doubt, consult with your local information technology support.

Adverse Reactions

- Patients may experience skin irritation and burns beneath the stimulation electrodes applied to the skin.
- Patients may experience headache and other painful sensations during or following the application of electrical stimulation near the eyes and to the head and face.
- Patients should stop using the device and should consult with their physicians if they experience adverse reactions from the device.

Warnings

- Do not apply stimulation over the neck because this could cause severe muscle spasms resulting in closure of the airway, difficulty in breathing, or adverse effects on heart rhythm or blood pressure.
- Do not apply stimulation across the chest because the introduction of electrical current into the chest may cause rhythm disturbances to the heart, which could be lethal.

- Do not apply stimulation over open wounds or rashes, or over swollen, red, infected, or inflamed areas or skin eruptions (e.g., phlebitis, thrombophlebitis, varicose veins).
- Do not apply stimulation over, or in proximity to, cancerous lesions.
- Do not apply stimulation in the presence of electronic monitoring equipment (e.g., cardiac monitors, ECG alarms), which may not operate properly when the electrical stimulation device is in use.
- Do not apply stimulation when in the bath or shower.
- Do not apply stimulation while driving, operating machinery, or during any activity in which electrical stimulation can put the patient at risk of injury.
- Consult with the patient's physician before using this device, because it may cause lethal rhythm disturbances to the heart in susceptible individuals.
- Apply stimulation only to normal, intact, clean, healthy skin.
- No modification of this device is allowed.

APPENDIX H: Symbols



User Manual/device labeling



Type BF Applied Part



WEEE (Waste Electronic and Electrical Equipment) symbol in accordance with council directive 2002/96/EC

MN

Abbreviation for model number

APPENDIX I: Electromagnetic Compatibility Declaration

SENSUS is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.

| Emissions test | Compliance | Electromagnetic environment – guidance |
|--|---------------------------|---|
| RF emissions; CISPR 11 | Group 1 | SENSUS uses RF energy only for its internal function. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions; CISPR 11 | Class B | SENSUS is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes. |
| Electrostatic Discharge Immunity (ESD); IEC 61000-4-2 | ±6kV contact; ±8kV air | Floors should be wood, concrete or ceramic tile. |
| Radiated RF; IEC 61000-4-3 | 3 V/m; 80 MHz to 2.5 GHz | 3 V/m compliance level |

NEURO**Metrix**[®]

62 Fourth Avenue
Waltham, MA 02451
(888) 786-7287
www.SENSUSRx.com

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